

The Independent Information Center **Rx** Health Value

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061, (HFA-305)
Rockville, MD 20852

Docket No. 00N-1256

FDA Regulation of OTC Drug Products Hearing

Contact information:
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Sponsoring organization: RxHealthValue
Requested time: 15 minutes on either day

To Whom It May Concern:

I am writing to request an opportunity to testify at the hearings on June 28 and June 29 in Gaithersburg Maryland. RxHealthValue is a not for profit organization comprised of consumer groups, labor unions, employers, health plans and insurers which conducts research and provides information on the value of prescription drugs. I would like to provide testimony on safety criteria and standards for switching drugs which are currently available only by prescription to over the counter (OTC). I will be providing research findings on standards used in European Union nations, Canada, New Zealand and Australia as a way of determining normative public health and pharmacoepedimiological standards to inform regulatory practices in the US. I will also be providing documentation, where possible, of arguments and evidence provided by pharmaceutical companies to encourage the regulatory entities in those countries to switch drugs from prescription to over the counter.

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If you have any questions, please feel free to call me at 510-486-0636.

Sincerely,

A handwritten signature in black ink, reading "Mark Cloutier". The signature is written in a cursive, flowing style.

Mark Cloutier
Project Director

BACKGROUND

What: RxHealthValue Center – is an organization of major private-sector stakeholders committed to sponsoring research, educating the public and recommending private and public sector solutions to assure that the public realizes the health and economic value of prescription drugs.

Purpose: The organization is committed to:

- Sponsoring research to inform and educate consumers, providers, employers, government and third-party payers about the benefits and costs of prescription drugs as they contribute to overall health;
- Proposing solutions in the market for prescription drugs that encourage competition, foster appropriate and safe utilization of drugs and encourage innovation that improves the health of the population; and
- Encouraging the creation of independent, nationally prominent, scientifically-based entities to conduct clinical research regarding the value of specific drugs or of specific therapeutic classes.

What Makes it Unique: More than 30 groups of payors and users – representing consumers, unions, health plans, advocates, employers and clinicians – committed to determining what information is necessary to make wise choices about prescription drug options.

Who: Organizational Members Include: AARP, Academy of Managed Care Pharmacy, AFL-CIO, AFSCME, Alliance for Community Health Plans (not-for-profit health plans), American Medical Group Association, American Hospital Association, Blue Cross/Blue Shield Association (48 Blues Plans), General Motors, GTE Corporation, Kaiser Permanente, Lahey Clinic, Managed Health Care Association, Midwest Business Group on Health, National Consumers League, National Council of Senior Citizens, National Institute of Health Care Management, PCS Health Systems, Inc., United Automobile Workers, US West, Washington Business Group on Health and several distinguished **individual members** including Stuart Altman, Ph.D., Schneider Institute for Health Policy, Brandeis University; Christine K. Cassel, MD, Chair, Department of Geriatrics, Mt. Sinai Hospital and School of Medicine; Alain Enthoven, Ph.D., Graduate School of Business, Stanford University, Arnold Milstein, MD, William M. Mercer, Inc. and Ira Ockene, MD, University of Massachusetts Medical Center.

Results of First Research: A new study, by the Brandeis University Schneider Institute for Health Policy and PCS Health Systems, Inc., examines factors that contributed to the recent escalation of prescription drug spending nationally. The main study finding: Prescription drug costs grew at an annual rate of 24.8% (age-adjusted) per year from 1996-1999. The actual experience from the study population showed a higher percentage increase -- 28.8% -- because the PCS data is based on a fixed population, which aged during the study period.

Key Findings: For the purposes of the study, drugs were examined in two categories: drugs that were on the market in 1996, and those that were introduced after 1996. With respect to drugs being prescribed in 1996, the relative contributions to the overall increases in Rx expenditures from 1996-1999 were:

- Increases in number of prescriptions per user – 38.4%

- Increases in number of days per prescription – 19%
- Increases due to substitution of newer, more expensive drugs for existing drug therapy – 17.2%
- Number of new users (individuals not previously treated by prescription drugs) -- 14%
- Increases in price – 4.4%
- Interactions * – 7.0%
- Drugs introduced after 1996 account for about 1/3 of the increase in Rx expenditures from 1996-1999
- The proportion of persons with medication expenditures greater than \$2,000 per year has grown four-fold, from 1.3 percent of the population to 5.3 percent

Recommendations:

- Establishment of independent research institutes to determine comparative clinical value of prescription drugs;
- Development of voluntary national standards for risks/benefits information disclosure in direct-to-consumer advertising of prescription medications, and
- Improved post-marketing monitoring of adverse drug reactions, especially of “fast track” drugs, by the FDA.

Next Steps:

- Continue research efforts to add insight to the debate on prescription drug value issues;
- Examine the prescription drug market to assure consumers maximize value with respect to existing drugs and potential new therapies; and
- Develop new, meaningful ways to talk about and make value comparisons, especially within drug classes using a comparative model; and
- Encourage a better way of talking about risk/benefit/worth questions in active partnership with consumers.

For more information contact John Golenski, Ed.D. or Mark Cloutier, MPH, MPP at 510-486-0636.

* Part of expenditure growth that does not fall discretely into price or quantity, but may be part of both.